

Appln. No.: 10/563,659
Amendment Dated December 22, 2008
Office Action of September 22, 2008

BPD-102US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No: 10/563,659
Applicant: Peter Schwind *et al.*
Filed: February 20, 2007
Title: DEVICE AND METHOD FOR SIMULTANEOUSLY IDENTIFYING
BLOOD GROUP ANTIGENS
T.C./A.U.: 1641
Examiner: Nguyen, Bao Thuy L
Confirmation No.: 5376
Docket No.: BPD-102US

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF DR. PETER SCHWIND PURSUANT TO 37 CFR §1.132

I, Dr. Peter Schwind, being duly warned that willful false statements and the like are punishable by fine or imprisonment or both, under 18 U.S.C. §1001, and may jeopardize the validity of the patent application or any patent issuing thereon, state and declare as follows:

1. All statements herein made of my knowledge are true and statements made on information and belief are believed to be true.
2. Exhibits A and B attached hereto are incorporated herein by reference.
3. I received my Ph.D. degree in Science at the Universität Konstanz, located in Constance/Germany in 1993. I received my Diploma degree in Science at the Universität Konstanz, located in Constance/Germany in 1989. I received my School leaving examination at the Riemenschneider-Gymnasium, located in Wuerzburg/Germany in 1981.
4. I have been employed by Medion Diagnostics of Duedingen/Switzerland for seven years. I am Managing Director. I am directly responsible for Research and Development and Intellectual Property. Further, all department Managers (Manufacturing, Quality Assurance and

Appln. No.: 10/563,659
Amendment Dated December 22, 2008
Office Action of September 22, 2008

BPD-102US

Regulatory Affairs, Materials/Purchase/Planning, Customer Service, Marketing and Sales, Human Resources are reporting to me. The device in question I invented in 2002, when I was Head of Research and Development at Medion Diagnostics and Managing Director at Prisma Diagnostika. A copy of my *curriculum vitae* is attached hereto as Exhibit A.

5. I am a named Inventor on this patent application.

6. I have read and am familiar with the contents of this patent application and the Office Action dated September 22, 2008. I understand the nature of the written description and indefiniteness rejections at issue in this application is that the Office has asserted there must be a divider or barrier separating multiple flow tracks on a single membrane, and has asserted it is not clear how different flow tracks can be present on a single membrane without any divider or barrier separating them. This declaration addresses these issues.

7. A device according to the invention can be configured with an application zone positioned between two or more groups of indicator zones, for example, in the center of the device. Exhibit B, which shows a frame-by-frame operation of an exemplary device according to a preferred embodiment, illustrates this configuration (page 1). Page 2 of Exhibit B shows a liquid sample added to the application zone, and pages 3-6 show the sample diffusing outward through two groups of indicator zones without cross-contamination of each respective group. Page 7 shows the groups of indicator zones arranged according to a preferred embodiment; excess sample was removed by washing.

The indicator zones are on a single membrane, no divider or barrier separates each group of indicator zones, and at least two indicator zones within each group are substantially parallel to each other absent a physical separator between them. Thus, it is possible to position the groups of indicator zones such that the liquid sample flows through only a single group without the need for a divider or barrier preventing cross-flow into the other group, and it is possible to position the indicator zones substantially parallel to each other without the need for a divider or barrier between them.

8. Exhibit B demonstrates that a single membrane does not require a physical separator to have multiple flow tracks without cross-contamination of the tracks. The Office Action, therefore, is not correct in its assertion that a divider or barrier is required, and is not correct in

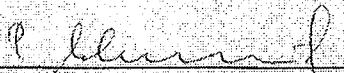
Appln. No.: 10/563,659
Amendment Dated December 22, 2008
Office Action of September 22, 2008

BPD-102US

Its assertion that it is unclear how different flow tracks can be present on a single membrane without a divider or barrier separating them.

9. A device according to Application 10/563,659 has been commercialized since 2006 in several countries (e. g. Germany, Switzerland, United Kingdom, Greece, Russia and others) and many thousands of cards have been used by professionals to determine multiple (10) blood groups in parallel -particularly for emergency patients before blood transfusion- without reported cross contamination or transfusion errors.

Date: 17. 12. 2008


Dr. Peter Schwind

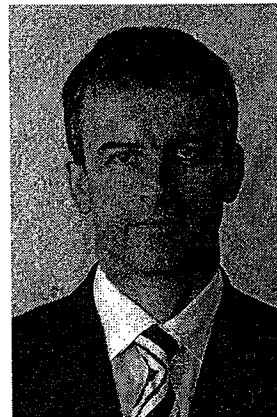
Attachments: Exhibit A and B

EXHIBIT A

Curriculum Vitae

General

Name: Dr. Peter Schwind
Chemin du Calvaire 4
1700 Fribourg, Switzerland
Date of Birth: 04 July 1962
Citizenship: German
Civil State: Married, 1 son and 1 daughter
Tel: +41 26 322 72 45
E-Mail: peter.schwind@freesurf.ch



Formation

1968-1981: Primary and High School: Würzburg/Germany
1981-1983: Civil Service as Male Nurse at the Psychiatric Hospital of the University of Würzburg/Germany
1983-1989: Study of Biology at the University of Constance/Germany
1989: Diploma Degree at the Department of Biochemistry at the University of Constance/Germany
1989-1993: PhD work at the Department of Biochemistry at the University of Constance/Germany

Professional

1983: Male nurse at the Psychiatric Hospital of the University of Würzburg/Germany
1989-1992: Scientific translations of Medical Publications for "Dr. E. Kraus Communicating Biomedicine", Paris/France
1989-1993: Scientific Employee at the University of Constance
1993: Post Doctoral Fellowship at the department of Physical Chemistry at the University of Constance/Germany
1993-1999: Project Manager R&D at DiaMed AG, Cressier sur Morat/Switzerland
2000-2001: Vice President at DiaMed Applied Diagnostics Systems AG, Cressier sur Morat/Switzerland (a daughter company of DiaMed Holding AG)
Since 01/2002: Head of R&D at Medion Diagnostics GmbH, Düringen/Switzerland
2002-2004: Managing Director of Prisma Diagnostika GmbH, Berlin/Germany
Since 07/2004: Managing Director of Medion Diagnostics GmbH, Düringen/Switzerland, heading R&D, IP (directly), Production, QC, QA and Regulatory Affairs (indirectly)
Since 10/2005: Acting Partner of Medion Diagnostics GmbH after Management Buy-Out
Since 02/2006: Acting Partner of Medion Diagnostics AG, Düringen/Switzerland, heading R&D, IP (directly), Production, QC, QA, Regulatory Affairs, Finance, Controlling, Human Resources/Administration, Materials and Purchasing, Marketing and Sales (indirectly).

Languages

German native language
English spoken and written
French spoken and written
Spanish basic knowledge
Italian basic knowledge
Scientific lectures/presentations done in English, German, French and Spanish.

Memberships

AABB – American Association of Blood Banking
ISBT – International Society of Blood Transfusion
DGTI – Deutsche Gesellschaft für Transfusionsmedizin und Infusionstherapie

Award

2005 Special Award for Medion Diagnostics GmbH at the Innovation Price of the Kanton of Fribourg: "New Device for the Multiparameter Determination of Blood Groups without Centrifugation (MDmulticard)"

Leisure

Family, Cooking, Wine, Sports (bicycle), gardening.

Publications

Granted Patents and Patent Applications

1. **Schwind P, Bashforth D, Hobbs R, Margetts G, Marshall M, Roberts M. (1996).** Synthetische Partikel als Agglutinationsreagentien. EP 0 849 595
2. **Schwind P, Bashforth D, Hobbs R, Margetts G, Marshall M, Roberts M. (1997).** Synthetic particles as agglutination reagents US 6,203,706
3. **Schwind P., Becker H. (2002).** Trägerelement für diagnostische Tests. DE10244154.5-52.
4. **Schwind P., Becker H. (2003).** Trägerelement für diagnostische Tests. PCT/EP03/10590.
5. **Schwind P., Löster K. (2003).** Vorrichtung für Lateral-Fluss-Tests. DE10330983.7.
6. **Schwind P., Löster K. (2003).** Vorrichtung und Verfahren zur simultanen Durchführung von Blutgruppenbestimmung, Serumgegenprobe und Antikörpersuch-Test. DE10330981.0-52.
7. **Schwind P., Löster K. (2003).** Vorrichtung und Verfahren zur simultanen Bestimmung von Blutgruppenantigenen. DE10330982.9-52.
8. **Schwind P. (2004).** Testelement und Verfahren zum Testen von Blut. DE 102004005139.9
9. **Schwind P., Monod P. (2004).** Vorrichtung und Verfahren zum Nachweis von Analyten durch Sichtbarmachung und Separation von Agglutination. DE 102004005193.3.
10. **Schwind P., Löster K. (2004).** Vorrichtung für Lateral-Fluss-Tests. PCT/EP2004/007526.
11. **Schwind P., Löster K. (2004).** Vorrichtung und Verfahren zur simultanen Durchführung von Blutgruppenbestimmung, Serumgegenprobe und Antikörpersuch-Test. PCT/EP2004/007525.
12. **Schwind P., Löster K. (2004).** Vorrichtung und Verfahren zur simultanen Bestimmung von Blutgruppenantigenen. PCT/EP2004/007536.
13. **Schwind P. (2005).** Testelement und Verfahren zum Testen von Blut. PCT/EP2005/001027.
14. **Schwind P., Monod P. (2005).** Vorrichtung und Verfahren zum Nachweis von Analyten durch Sichtbarmachung und Separation von Agglutination. PCT/EP2005/001029.
15. **Schwind P., Aebischer I. (2006),** Verfahren zur Bestimmung von minoren Zellpopulationen in heterogenen Zellpopulationen. DE102006062619.2.
16. **Schwind P., Aebischer I. (2007),** Verfahren zur Bestimmung von minoren Zellpopulationen in heterogenen Zellpopulationen. PCT/EP 2007/011016.

Registered Designs

1. **Schwind P., Becker H. (2002).** Trägerelement für diagnostische Tests. 20221515.6.

Peer-reviewed articles in Scientific Journals

1. **Tazzari P, Ricci F, Vitale M, Malferrari F, Salama A, Schwind P, Conte R (2002).** Heparin-induced thrombocytopenia: detection of antiheparin/PF4 antibodies by means of heparin/PF4 coated beads and flow cytometry. *Transfus Med* 12:193-8.
2. **Eichler P, Raschke, R, Lubenow N, Meyer O, Schwind P, Greinacher A (2002).** The new ID-heparin/PF4 antibody test for rapid detection of heparin-induced antibodies in comparison with functional and antigenic assays. *Br J Haematol* 116:887-891.
3. **Seltsam A, Schwind P, Abraham K, Hiepe F, Cygan S, Aebischer I, Salama A (2002).** Rapid detection of autoantibodies to dsDNA with the particle gel Immunoassay (ID-PaGIA). *Ann Rheum Dis* 61:367-9.
4. **Salama A, Schwind P, Schönhage K, Genth R, Cotting C, Hustinx H, Krieg R, Nydegger U, Aebischer I (2001).** Rapid detection of antibodies to IgA molecules using the particle gel immunoassay (ID-PaGIA) *Vox Sang* 81:45-8.

5. **Schwind P, Meyer O, Ayoub M, Aebischer I, Pittet N, Salama A (2000).** Point-of-care diagnosis of heparin-induced thrombocytopenia. *Lab Med* 1(4): 48-51.
6. **Ivanova VV, Kvetnaia AS, Skripchenko NV, Zhelezova LI, Schwind P, Tsygan S, Shavva SA (2000).** Diagnostic value of Diamed AG latex gel kit for detection of diphtheria toxin. *Klin Lab Diagn* 4:42-4.
7. **Meyer O, Salama A, Pittet N, Schwind P (1999).** Rapid detection of heparin-induced platelet antibodies with particle gel immunoassay (ID-HPF4). *The Lancet* 354:1525-6.
8. **Rabello A, Luquetti AO, Moreira EF, Gadelha MD, dos Santos JA, de Melo L, Schwind P (1999).** Serodiagnosis of *Trypanosoma cruzi* infection using the new particle gel immunoassay - ID-PaGIA Chagas. *Mem Inst Oswaldo Cruz* 94(1):77-82.
9. **Stewart MW, McKay T, Schwind P, Gordon PA (1998).** Rapid detection of anticardiolipin antibodies. *Am J Hematol* 57(4):315-9.
10. **Cohen B, Millar A, Schwind P (1995).** Screening blood donations for Parvovirus B19. *The Lancet* 346:1631.
11. **Kramer H, Graf C, Hagenbuchle M, Johner C, Martin C, Schwind P, Weber R (1994).** Electro-optic effects of aqueous fd-virus suspensions at very low ionic strength. *J Phys II France* 4:1061-1074.
12. **Svoboda M, Bauhofer A, Schwind P, Bade E, Rasched I, Przybylski M (1994).** Structural characterization and biological activity of recombinant human epidermal growth factor proteins with different N-terminal sequences. *Biochim Biophys Acta* 1206(1):35-41.
13. **Schwind P, Kramer H, Kremser A, Ramsberger U, Rasched I (1992).** Subtilisin removes the surface layer of the phage fd coat. *Eur J Biochem* 210(2):431-6.
14. **Schwind P, Rasched I (1992).** A new approach to investigate the particle structure of filamentous phages on the amino acid level. *J Prot Chem* 11(4):415-6.

Selected Abstracts

1. **Geisen C, Schwind P, Seifried E (2006).** Performance evaluation of a novel lateral flow device for rapid multi-parameter blood grouping without centrifugation. *Transfus Med Hemother.* 33 (suppl 1), 49.
2. **Gassner C, Körmöczí GF, Jungbauer C, Wessin D, Schwind P, Schennach H, Schönitzer D (2006).** Multi-variant genotyped donor panels in usage for performance comparison of three commercially available RHD/ABO serotyping methods. *Transfus Med Hemother.* 33 (suppl 1), 3.
3. **Geisen CG, Schwind P, Seifried E (2006).** Rapid multi-parameter blood grouping without centrifugation - performance evaluation with donor, patient and neonatal samples. *Transfusion* 46 (9S), 143A.
4. **Gassner C, Körmöczí GF, Jungbauer C, Wessin D, Schennach H, Schwind P, Schönitzer D (2006).** Multi-variant genotyped donor panels in usage for performance comparison of three commercially available RHD/ABO serotyping methods. *Transfusion* 46 (9S), 142A-143A.
5. **Geisen CG, Schwind P, Seifried E (2006).** Performance evaluation study of a novel lateral flow assay for simultaneous typing of ABO, D, Rhesus subgroups and K ("MDmulticard"). *Vox Sang* 91 (Suppl. 3), 110-111.
6. **Gassner C, Körmöczí GF, Jungbauer C, Wessin D, Schennach H, Schwind P, Schönitzer D (2006).** Performance comparison of Medion-MDmulticard, ID-DiaMed and ScanGel-BioRad RHD/ABO serotyping using a multi-variant, Caucasian-specific, genotyped donor panel. *Vox Sang* 91 (Suppl. 3), 113-114.
7. **Aebischer I, Loester K, Monod P, Schwind P (2005).** ABO Forward and reverse typing with stable end-point without centrifugation. *Transfus Med Hemother* 32 (suppl 1), 55.
8. **Schwind P, Aebischer I, Löster K, Monod P (2005).** Complete ABO blood group with forward and reverse typing in a lateral flow device. *Transfusion* 45 (3S), 124A.

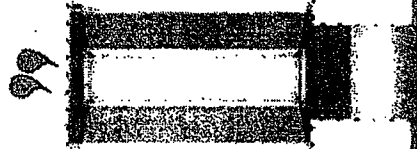
9. **Schwind P, Aebischer I, Loester K, Monod P, (2005).** Forward and reverse blood grouping with lateral flow based assays. *Vox Sang* 89 (Suppl. 1), 151.
10. **Schwind P, Fasel A, Monod P (2004).** New format for blood group serology diagnostics. *Transfusion* 44 (9S), 121A.
11. **Schwind P, Löster K (2004).** Point-of-care multi-parameter typing of 10 blood groups with stable end-point. *Transfusion* 44 (9S), 121A.
12. **Monod P, Fasel A, Schwind P (2004).** Capillary centrifugation for blood grouping with distinct areas for positive and negative reactions. *Vox Sang* 87 (Suppl. 3), 40.
13. **Löster K, Fleischhauer S, Schwind P (2004).** Lateral flow assay for simultaneous typing of ABO, Rhesus subgroups and Kell. *Vox Sang* 2004, 87 (Suppl. 3), 40.
14. **Schwind P, Tschopp M, Fasel A, Monod P, Willemin WA (2004).** Concept to coordinate laboratory ABD confirmation testing with ABO-identity bedside test. *Vox Sang* 87 (Suppl. 3), 138.
15. **Monod P, Fasel A, Schwind P (2004).** Capillary centrifugation for blood group serology diagnostics with distinct areas for positive and negative reactions. *Transfus Med Hemother* 31 (S3), 28.
16. **Löster K, Fleischhauer S, Zillmann S, Schwind P (2004).** Rapid multi-parameter typing of 10 blood groups with stable end-point. *Trans Med Hemother* 31 (S3), 28.
17. **Aebischer I, Löster K, Monod P, Schwind P (2004).** ABO-Identity Test for pretransfusion bedside testing in a lateral flow device. *Transfus Med Hemother* 31 (S3), 56.
18. **Eichler P, Raschke R, Lubenow N, Meyer O, Schwind P, Greinacher A (2001).** The new ID-Heparin/PF4 antibody test for rapid detection of heparin-induced antibodies in comparison with functional and antigenic assays. *Ann Hematol* 80 (S1), 1-15.
19. **Meyer O, Koster A, Salama A, Schwind P (2000).** The new ID-HPF4 for the detection of heparin-dependent platelet antibodies. *Transfusion* 40(10S), S18-030C.
20. **Meyer O, Salama A, Pittet N, Schwind P (2000).** Particle Gel Immuno-Assay (ID-HPF4) for Rapid Detection of Heparin-Dependent Platelet Antibodies. *Sang* 78(S1), P042.
21. **Salama A, Aebischer I, Genth R, Schonhage K, Schwind P (1999).** Rapid detection of antibodies against IgA molecules using particle gel Immunoassay (ID-PaGIA). *Infusion Therapy and Transfusion Medicine* 26(S1), 36.
22. **Schwind P, Brodard M (1998).** Screening of blood donors for Parvovirus B19 in the ID-System. *Vox Sang* 78 (S1), 1312.

EXHIBIT B

835/567ABD112002CD

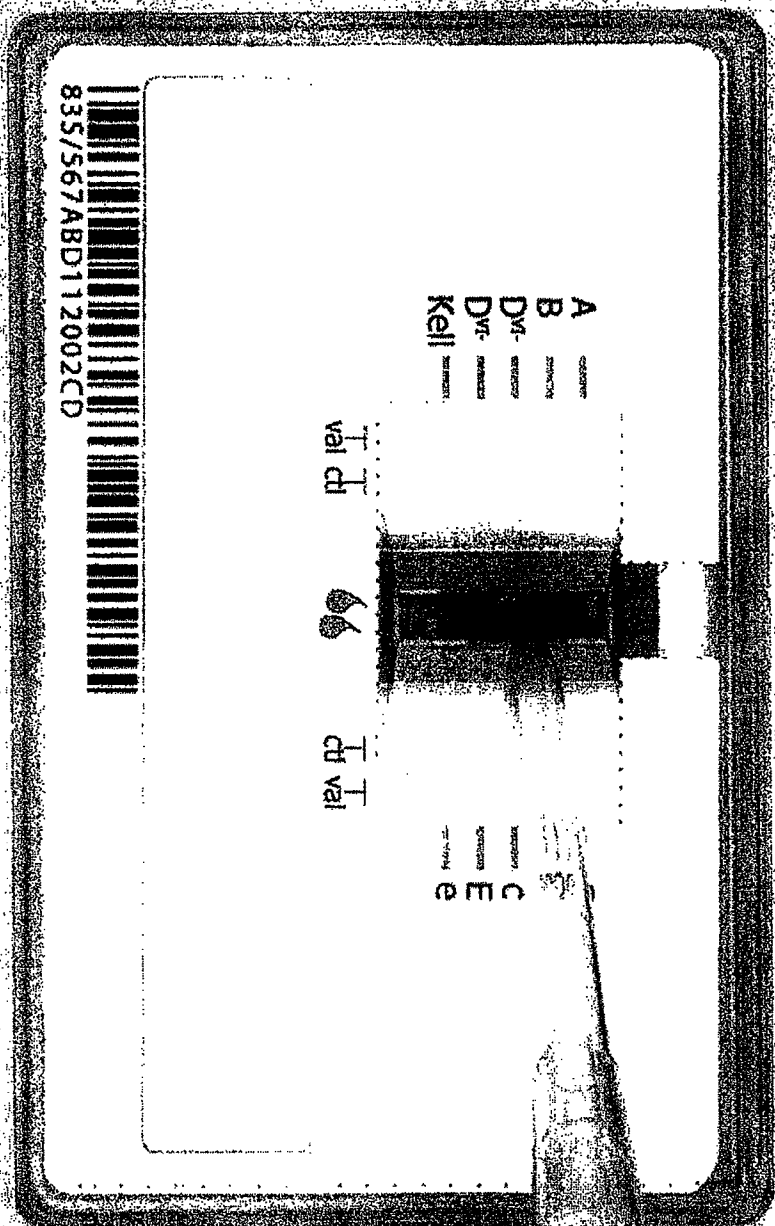
A
B
D₁
D₂
Kell

T
T
val di



T
T
di val

C
C_w
C_e
e



A
B
Dv
Dv
Kell

val di

di val

C
E
e



835/567ABD112002CD



835/567ABD112002CD

A
B
Dvr
Dvr
Kell

T
val



T
dt

C
Cw
C
E
e

835/567ABD112002CD

A
B
Dvr
Dvr
Kell

T
val



T
val

C
Cw
E
e



83S/567ABD112002CD

A
B
Dvt
Dvt
Kell

C
Cw
C
E
e

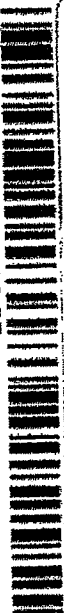
val dt dt val

A	11/15/2013
B	11/15/2013
D ^{WT}	11/15/2013
D ^{WT}	11/15/2013
KeH	11/15/2013

7-11

cu val

፳፻፲፱



835/567ABD112002CD

835/567ABD112002CD

A
B
Dyr
Dyr
Kell

T
val
dt

T
dt
val

C
Cw
C
E
e